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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,425	04/18/2006	Soo-Kyung Kim	74448.00003/P31590 USA	9237

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EXAMINER	
FORMAN, BETTY J	
ART UNIT	**PAPER NUMBER**
1634	

NOTIFICATION DATE	DELIVERY MODE
12/20/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,425	KIM ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,6,7 and 12-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,4,6,7 and 12-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 August 2010 has been entered.

Status of the Claims

2. This action is in response to papers filed 25 August 2010 in which claim 2 was amended and the previous rejections were traversed. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 24 February 2010 withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below.

New grounds for rejection, necessitated by the amendments, are discussed.

Claims 2, 4, 6, 7, 12-15 are under prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2, 4, 6, 7 and 12-15 are rejected under 35 U.S.C. 103(a) as obvious over Krutzik (U.S. Patent No. 7,141,416, filed 12 July 2002) in view of Sandstrom (U.S. Patent No. 6,545,758, issued 8 April 2003) and Wang et al (U.S. Patent No. 5,922617, issued 13 July 1999) and Yamatsu et al (U.S. Patent No. 7,709,248, published 18 December 2003).

Regarding Claim 2, Krutzik teaches a biochip readout device comprising a rotatable biochip cartridge (#110) having a biochip installed on the disc (e.g. microarray #147, Fig. 15, Column 13, lines 3-20). Krutzik further teaches a light reception means for receiving beam from the disc (i.e. focusing and tracking via bottom detector #157) having a light source scanning the disc (#150), a focusing/tracking control using the light reception means (Column 13, lines 21-52), an optical pick-up unit having a drive for moving the objective lens for focusing/tracking (Column 14, lines 21-44 and Column 15, lines 57-64), an optical pick-up device for analyzing the biosignals from the biochip (top detector #158, Column 12, lines 21-52, Fig. 16). Krutzik teaches the device comprises a system and output controlling unit for monitoring analysis information, processing the signal (#166/168, Column 13, lines 46-52). Krutzik further teaches the device compares signals to known and/or reference analytes (Column 17, lines 8-12 and 37-41) and

further that the device provides for automated analysis of physiological disorders (Column 1, lines 66-Column 2, line 8). All of this clearly suggests the device is a diagnostic device for monitoring and comparing database information.

Furthermore, computerized diagnostics was well known and routinely practiced in the art at the time the invention was made as taught by Sandstrom (Column 4, line 53-Column 5, line 34). Sandstrom teaches a device wherein all elements of biochip construction, use and analysis are provided within the computerized system whereby the information is efficiently processed, stored and/or interpreted (Column 5, lines 61-67). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the diagnostic analysis of Sandstrom to the device of Krutzik. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the well known benefit of efficient processing and interpreting as taught by Sandstrom (Column 5, lines 61-67).

Krutzik further teaches the device further comprising an optical recording unit (analyzer #168) for recording signals in response to trigger mechanism (#126/160) and output unit for producing analysis information (Column 3, lines 25-67) wherein the trigger mechanism prompts the system to data collection when the trigger marking are detected thereby selecting for readout vs general scanning (Column 13, lines 35-52) wherein the biodisc is attached to the cartridge using an adhesive (#118, Column 7, lines 21-24) wherein the disc is formed by spotting biocells within a groove (Column 19, lines 12-31 and Column 25, lines 42-47) wherein the reflective film is selectively reflect

allowing some light to pass and some light to be reflected (Column 15, lines 22-29, Fig. 20).

Krutzik further teaches the device wherein the cartridge is a disc in which depressed portions are formed (Fig. 17-18) wherein the biodisc (#140) is installed in depressed portions (Fig. 15, 17-18) wherein the biochip includes an adhesive layer (#118, Column 7, lines 21-24). Figure 15 provides a view of the capture zone (#140) in microarray format (#147) and further illustrates the capture zones (#140) positioned in depressed regions of the channel/adhesive layer (#118) and a semi-reflective layer (#143) between the depressed regions and optical disc. Figures 17-18 provide a side view of the biodisc wherein the capture zone (#140) is clearly positioned in a groove of the fluidic circuit and the semi-reflective layer is between the depressed regions (#130) and biodisc (#120). Krutzik does not specifically teach the semi-reflective film (#148) is a selective wavelength reflection film. However, the specification does not define the claimed “selective wavelength reflection film” over any other reflective film such as the semi-reflective metal of Krutzik. Furthermore, Yamatsu teaches as similar biodisc having a selective wavelength reflection film (2) under the capture zone (see Fig. 3) and teaches that the selected film provides for selective reflection from the servo-controlled operations thereby eliminating the loss of fluorescence from the samples (Column 6, lines 12-23). Hence, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the reflective film of Yamatsu to the optical disc of Krutzik for the expected benefit of eliminating loss of fluorescence from the samples as desired in the art (Yamatsu, Column 6, lines 12-23).

Additionally, Wang teaches a biodisc similar to that of Krutzik wherein the arrays are prepared separately and then positioned on the biodisc (Column 14, lines 35-59).

Krutzik further teaches the cartridge wherein the adhesive member provides a fluidic circuit (Column 7, lines 36-39), but does not specifically teach that the biochip cannot be separated when the disc is rotated. However, sealed cartridges providing controlled assay environments were well known as taught by Sandstrom (Column 32, lines 40-47). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the cartridge of Krutzik to perform the arrays as taught by Wang and subsequently seal the cartridge while in use as taught by Sandstrom. One of ordinary skill in the art would have been motivate do so for the well known benefits of controlled assay environments as desired in the art (Sandstrom, Column 32, lines 40-47).

Regarding Claim 4, Krutzik teaches the device wherein the signal generation unit scans the biochip cartridge with light in response to control unit (via trigger mechanism) using a single light source while controlling focusing and tracking (Column 13, lines 21-52 and Column s 14-15).

Regarding Claim 6, Krutzik teaches the device wherein a fluorescent signal is detected (Column 2, lines 60-63) and compared to known reference or concentration (Column 17, lines 9-12 and 37-41) and further teaches the device monitors and processes information (Column 3, line 25-Column 4, line 12) thereby teaches the structural elements required by the claim.

Regarding Claim 7, Krutzik teaches the device detects fluorescence, but is silent regarding a fluorescence filter. However, Sandstrom teaches the device further comprising an emissions filter and detector (i.e. collection optics Column 34, lines 47-65).

Regarding Claim 12-14, Krutzik and Sandstrom teach the elements of Claim 7 as discussed above. Krutzik further teaches the device wherein a pin-spotter is used for patterning (Column 25, line 45) and Sandstrom also teaches a pin-spotter used for patterning (Column 23, lines 5764). The references do not teach a servo device for rotating the substrate at a predetermined speed while spotting and a controlled unit for controlling the servo device. However, servo devices providing controlled rotation while spotting a pattern onto the substrate was known in the art as taught by Wang.

Wang teaches a biochip readout device similar to that of Krutzik, the device comprising a rotatable biochip cartridge (#74) having a biochip installed on the disc (e.g. segment #70, Fig. 5, Column 14, lines 35-44). Wang further teaches a light reception means for receiving beam from the disc (i.e. focusing, tracking & header detector #134/136) having a light source scanning the disc (#102, Column 11, lines 40-67), a focusing/tracking control using the light reception means (Column 15, lines 28-45), an optical pick-up unit having a drive for moving the objective lens for focusing/tracking (Column 15, lines 32-36), an optical pick-up device for analyzing the biosignals from the biochip (#124, Column 15, lines 45-58, Fig. 7) and a system and output controlling unit for monitoring analysis information, processing the signal (Column 17, lines 13-55).

Wang further teaches the device comprising a patterning device (printer) comprising a servo device for rotating the disc (raster scanner) and a printer for patterning the biocell on the substrate and a controller (servooptics) for controlling the entire system for rotation and printing (Column 12, lines 33-43 and Column 17, lines 24-47).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the controlled servo device of Wang to the device of Krutzik to thereby provide for patterned spotting using controlled rotation at constant speed to provide desired pattern on the substrate as taught by Wang (Column 12, lines 33-43). Wang teaches that using the same elements to align the biodisc for printing and detecting the array precisely and rapidly aligns the biochip (Column 12, lines 33-43). Therefore, one of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the benefit of rapid positioning as taught by Wang (Column 12, lines 33-43.

Regarding Claim 15, Sandstrom further teaches the device further comprising a communication device for transmitting analysis and signal information to a readout device (Column 4, lines 53-67).

Response to Arguments

5. Applicant argues that the recessed portions of Krutzik are formed in the reflective layer not and not on it as claimed.

The argument has been considered however, Krutzik specifically illustrates the capture zone (140) formed in depressed regions of the channel/adhesive layer (Fig. 15,

17-18) and on semi-reflective layer (#143). Figure 15 provides a view of the capture zone (#140) in microarray format (#147) and further illustrates the capture zones (#140) positioned in depressed regions of the channel/adhesive layer (#118) and a semi-reflective layer (#143) between the depressed regions and optical disc. Figures 17-18 provide a side view of the biodisc wherein the capture zone (#140) is clearly positioned in a depressed region of the fluidic circuit and the semi-reflective layer is between the depressed regions (#130) and biodisc (#120). Therefore, Krutzik specifically teaches the reflective layer between the depressed region and disk as claimed.

Applicant further argues that Krutzik does not teach the depressed regions are formed in a first or second uppermost layer of the biochip cartridge.

The argument is not found persuasive. Krutzik illustrates the three components of the disk, cap portion (#116), channel/adhesive layer (#118) and substrate (#120) (see Fig. 2). The channel/adhesive layer is the second uppermost layer and has depressed portions as claimed. Therefore, Krutzik teaches the elements as claimed.

Applicant argues that Krutzik teaches integrated target zones but does not teach removably installed biochips as claimed. Applicant further argues that modification of the integrated target zones would changes the principle operation of the Krutzik disk. Applicant points to columns 20-21 to support the integrated feature of Krutzik. The argument is not found persuasive. While the reference teaches an embodiment wherein the capture agent is attached to chemical layers 144 as illustrate in Fig. 26, the reference is not limited to this embodiment. As cited in the Office Action, Krutzik

teaches an embodiment comprising capture zones (140) which differ from the active layer (144) as cited by Applicant (see Column 13, lines 3-10 below);

> FIG. 15 is a view similar to FIG. 14 showing an alternate embodiment of the transmissive reservoir optical bio-disc using optical bio-discrete capture zones 140 rather than an active layer 144. The optical bio-discrete capture zones 140 may be positioned at any pre-determined locations on the metal layer 143 …

It is maintained that one of ordinary skill in the art would have been motivated to position the capture zones using techniques found in the prior art based on the suggestion of Krutzik to position the capture zone at pre-determined locations.

Conclusion

6. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner
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